U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Brainlab Cranial Image-Guided Surgery (IGS) System – Navigation Inaccuracy

The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.

Recalled Product:

- Brainlab Cranial IGS System
- Brainlab Cranial Navigation Systems (all existing versions before Cranial 3.0)
- Distribution Dates: May 1996 to May 2015
- Devices Recalled in the U.S.: 1021units **Nationwide**

Device Use: Brainlab Cranial IGS System shows the area of interest and the position of an instrument relative to the patient's anatomy to enable minimally invasive surgical procedures.

Reason for Recall: Brainlab is recalling the Cranial IGS System due to potential inaccuracies in the display by the navigation system compared to the patient anatomy. This could lead to inaccurate, ineffective medical procedures, and serious life-threatening injuries including death.

Who may be affected:

- Health care providers using the Brainlab Cranial IGS System.
- All patients who may undergo a procedure with the use of the Brainlab Cranial IGS System.

What to Do:
Brainlab notified customers of the issue on April 22, 2013 and issued an update on May 29, 2015.

The notification indicates:

1. Customers should adhere to the Instructions for Use supplement document "Measures to Improve Cranial Navigation Accuracy" when using the affected product.
2. Brainlab will provide customers with an updated software version and schedule the update installation starting in September 2015.

Contact Information: Questions should be directed to Brainlab Customer Hotline: 1-800-597-5911 or by email **support@Brainlab.com (mailto:support@Brainlab.com)**.

Date Recall Initiated: April 22, 2013

How do I report a problem?
Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to **MedWatch: The FDA Safety Information and**

Adverse Event Reporting Program (https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) either online, by regular mail or by FAX.

Device Distribution:
The affected product was distributed in the following states:

- Arkansas (AR)
- California (CA)
- Colorado (CO)
- Maryland (MD)
- North Carolina (NC)
- Ohio (OH)
- Pennsylvania (PA)
- Texas (TX)

More in Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/default.htm)

2016 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm480134.htm)

2015 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm429489.htm)

2014 Medical Device Recalls (/MedicalDevices/Safety/ListofRecalls/ucm384921.htm)